action of an invention to satisfy either the written description or the enablement requirements of §112, and indeed many important and valuable inventions have been patented without any knowledge of mechanism.

As for the written description requirement, it is sufficient that the specification "clearly convey to those skilled in the art, to whom it is addressed, in any way, the information that the applicant has invented the subject matter later claimed." *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976), appeal after remand, 646 F.2d 527 (CCPA 1981). In the present case, the specification clearly conveys to the skilled artisan that the applicants have invented the claimed invention. Twenty-five pages of detailed description (pages 6-31) describe the invention of claims 1-28 and 102-103. Working examples in the specification show that the invention has been made. If one of ordinary skill would follow the written description, that skilled artisan would see that the invention has been adequately described, because success would be obtained, as demonstrated in the declaration of Dr. Todd Milne, filed 21 November 2001.

In fact, the specification is not devoid of mechanistic information. A number of variables affecting secondary metabolism are described (p.6, last paragraph – p.7, l. 7). Pathways from which the secondary metabolites are derived are described (p. 7, l. 10-16). Particular useful genes are described (p.9, l. 8-22). Particularly useful types of mutations are described (p.10, l. 7-p.12, l.12). Some pathway regulation information is provided in Figure 2. The Examples illustrate how to use this information in practical ways.

Notwithstanding the foregoing, it simply is not necessary under the law for the inventors to describe, or even to know, the complete pathways of all secondary metabolism to provide adequate written description for the claimed invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The specification also enables one skilled in the art to make and use the invention. The experiments described in the Examples and the experiments described in Dr. Milne's declaration (using the guidance provided by the specification) demonstrate that the invention, as claimed and

described in the specification works without undue experimentation. At page 5 of the office action, lines 5-6, Dr. Milne's declaration is criticized because it does not describe what metabolic pathways are modulated in his successful experiments. As discussed above, it does not matter. The claimed invention is not a scientific explanation for how secondary metabolism is improved. The claimed invention is a method for improving secondary metabolism. What matters is that the claimed method works, and works without undue experimentation.

The office action relies heavily on an article by Parekh et al for the proposition that the claimed invention requires undue experimentation. However, this reference focuses on traditional methods of fungal strain improvement (e.g. random mutagenesis and screening) and there is no evidence of record that Mr. Parekh is skilled in the art of the molecular biology of fungi, the field to which the invention relates. At page 8, lines 22-24 the specification states "The modulation is not achieved, however, by simply randomly mutagenizing the fungus, either spontaneously or by chemical means." Regardless of the status of Mr. Parekh's expertise, however, Applicants have overcome the statements relied upon in the Office Action with objective evidence that undue experimentation is not required, and can continue to provide further such evidence if required.

Relying primarily on Parekh et al., the Office Action at page 7 states that the claimed invention is an empirical approach, and that "An empirical approach constitutes undue 'trial and error' experimentation." This, however, is not the law. In *Atlas Powder Co. v. E.I. du Pont de Nemors & Co.*, the Court of Appeals for the Federal Circuit held that a district court did not err in finding the patent specification enabling even though it listed elements that could form thousands of end products, some of which may not be operative. "That some experimentation is necessary does not preclude enablement, the amount of experimentation, however, must not be unduly extensive." 750 F.2d 1569 (Fed. Cir. 1984).

In the Supplemental Declaration of Dr. G. Todd Milne, attached hereto, Dr. Milne states that each of the experiments described in his previous declaration required about 5 hours, on

average, to achieve success. He also states that a large number of such experiments, using numerous different regulators can be done in parallel, allowing a very large number of regulators to be tested in a relatively short time. Applicants respectfully submit that while this does constitute some experimentation, it is not undue. Accordingly Applicants request that the rejection for nonenablement be withdrawn.

For the reasons discussed above, Applicants respectfully submit that claims 1-28, 102 and 103 are now ready for allowance. If the Examiner believes that any discussion of this reply would be helpful, the Examiner is invited to call the undersigned attorney by telephone at 781-938-1805.

Respectfully submitted,

Dated: 6/6/02

W.A.K

Wayne A. Keown, Ph.D.
Registration No. 35,923

LAW OFFICES OF
WAYNE A. KEOWN
500 West Cummings Park
Suite 2900
Woburn, MA 01801
781-938-1805 (Telephone)
781-938-4777 (Facsimile)